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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/331,127	10/19/1999	DONALD G. MUNROE	016777-0344	1284

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EXAMINER	
HAMUD, FOZIA M	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 08/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/331,127	MUNROE ET AL.	
	Examiner	Art Unit	
	Fozia M. Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-43* is/are pending in the application.

4a) Of the above claim(s) *36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-35 and 37-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *07/07/00*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1a. The amendment filed on 19 July 2006 has been entered. Also the amendment to the specification filed on 20 September 2004, does not appear to introduce new matter.

Status of Claims:

1b. Claims 1-19 have been cancelled and new claims 20-43 have been added. Thus claims 20-43 are pending.

Election/Restriction:

1c. Applicants elect the invention of Group I (original claims 1-2, and 5-12, 14, 16 in part), in the response filed on 19 July 2006. Although, Applicants state that the election is with traverse, Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Furthermore, Applicants state that all the new claims are drawn to the elected invention, however, such is not the case. The invention of Group I is drawn to an isolated polynucleotide encoding the GLP-2 receptor of SEQ ID NO:12, said polynucleotide comprising the nucleotide sequence set forth in SEQID NO:11, a cell comprising said polynucleotide and a recombinant GLP-2 of SEQ ID NO:12 and a method of identifying ligands for GLP-2 by using the cell comprising the nucleotide of SEQ ID NO:11. However, new claim 36 is drawn to an antibody.

Claims 20-43 are pending, of which claims 20-35, 37-43 are drawn to the elected invention, and will be searched and examined. Claims 36 is withdrawn from consideration by the Examiner as they are drawn to non-elected invention.
The restriction requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement:

2. The information disclosure statement (IDS) submitted 07 July 2000 was received and complies with the provisions of 37 CFR §1.97 and §1.98. It has been placed in the application file and the information referred to therein has been considered as to the merits. However, there are other references filed in the current application on 14 June 1999. If Applicants wish for these references to be considered, the references must be listed on an information disclosure statement form to comply with the provisions §1.98.

Claim rejections- Double patenting:

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

3a. Claim 25 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 4 of prior U.S. Patent No. 6,077,949. This is a double patenting rejection.

Claim rejections- Obviousness-type Double patenting:

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3b. Claims 20-35, 37, 41-43 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 3, 4, 7, 8, and 9 of U.S. Patent No. 6,077,949. Although the conflicting claims are not identical, they are not patentably distinct from each other because: instant claims 20-35, 37, 41-43 are drawn to an isolated polynucleotide comprising the nucleotide sequence of 320-1780 of SEQ ID NO:11, encoding the amino acids 67-553 of SEQ ID NO:12 or encoding amino acids 26-553 of SEQ ID NO:12, or encoding a polypeptide that is at least 95% identical to SEQ ID NO:12. While claims 41-43 are drawn to an isolated polynucleotide having nucleotide sequence that is at least 80%, 90% or 95% to SEQ ID NO:11, and a host cell comprising said nucleic acid.

Claims 1, 2, 3, 4, 7-9, of U.S. Patent No. 6,077,949 (having the same inventor entity as the instant application), are drawn to an isolated polynucleotide comprising the nucleotide sequence set forth in SEQ ID NO:11, which encodes the polypeptide of SEQ ID NO:12, a host cell comprising said nucleic acid. Instant claims encompass an isolated polynucleotide which encodes the human GLP-2 receptor comprising the amino acid sequence of SEQ ID NO:12, and variants of said receptor or polynucleotide which encodes amino acids 67-553 of SEQ ID NO:12, or amino acids 26-553 of SEQ ID NO:12. While claims of U.S. Patent No. 6,753,166 are drawn to the full length polynucleotide, of SEQ ID NO:11 encoding the full length GLP-2 receptor of SEQ ID NO:12. However, the claimed polynucleotide and the polynucleotide of the patented claims are the same, since they encode the same protein, i.e the GLP-2 receptor of SEQ ID NO:12. Thus, the patented claims are drawn to species of the invention claimed in the instant application claims. Therefore, claims 1, 2, 3, 4, 7-9 of U.S. Patent No. 6,077,949 anticipate instant claims 20-35, 37, 41-43, since species will anticipate a claim to a genus. Accordingly, allowance of the pending claims, would have the effect of extending the enforceable life of the allowed claims beyond statutory limit.

Claim Rejections Under 35 U.S.C. § 112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4a. Claims 20, 27, 28-35, 37-43 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling an isolated polynucleotide comprising a

nucleotide sequence set forth in SEQ ID NO:11 encoding the protein comprising the amino acid sequence set forth in SEQ ID NO:2, a host cell that has been genetically engineered by the incorporation expressibly, therein of said polynucleotide, and a method of identifying ligands for GLP-2 by using said cell, does not reasonably provide enablement for a mammalian homolog or a variant of the polypeptide of SEQ ID NO:12, or a polypeptide which is at least 80%, 90% or 95% sequence identity, which selectively binds to GLP-2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 20 encompasses an isolated polynucleotide encoding a variant of the polypeptide of SEQ ID NO:12 or a mammalian homolog, wherein said variant comprises one amino acid substitution, while claims 32-38 encompass cell comprising said nucleic acid and method of using said cell. Claim 27 encompasses an isolated polynucleotide encoding a polypeptide having at least 95% to the polypeptide of SEQ ID NO:12, while claims 41-43 are drawn to a polynucleotide that is at least 80%, 90% or 95% to the polynuceltide of SEQ ID NO:11, which encodes a GLP-2 receptor that binds to GLP-2. Claims 28-31 encompass an isolated polynucleotide which hybridizes under un-specified conditions to the nucleic acid of SEQ I NO:11. Claims 39-40 encompass method of identifying ligand for GLP-2 receptor, by using a cell expressing un-specified GLP-2 receptor.

The instant specification discloses an isolated nucleic acid comprising the nucleotide sequence set forth in SEQ ID NO:11, which encodes the polypeptide of SEQ ID NO:12.

The specification discloses that the polypeptide of SEQ ID NO:12 binds to GLP-2, (see page figure 8). The specification discloses a variant, wherein the arginine at position 85 is replaced with a glutamic acid and states that this variant is a functional receptor, (see p age 10, lines 10-13). Although the instant specification does not demonstrate that the Glu85 receptor variant binds to GLP-2 or exhibits other GLP-2 receptor activities, one of ordinary skill in the art would be able to make this variant and test it for activity. The specification does not enable other variants with one amino acid substitutions, other the one that arginine 85 is replaced with glutamic acid. The specification fails to disclose other variants or mammalian homolgs of SEQ ID NO:12 that bind to GLP-2 or exhibit any of the functional activities of said receptor. Regarding claims 27 and 41-43, the specification does not disclose a polypeptide that shares the recited percent identity with SEQ ID NO:12, or a nucleic acid which shares 80%, 90% or 95% to SEQ ID NO:11, which encodes a protein that retains the desired function.

Regarding claims 28-31, the specification does not enable an isolated polynucleotide which hybridizes under un-specified conditions to the nucleic acid of SEQ ID NO:11, that would retain the functional integrity of SEQ ID NO:11. The factors to be considered have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art and the breadth of the claims. Ex Parte Forman, (230 USPQ 546 (Bd Pat. App. & Int. 1986)); In re Wands, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988). In the instant case, Applicant only disclose the

polypeptide of SEQ ID NO:12, encoded by the polynucleotide of SEQ ID No: 11. However, Applicant has not described the characteristics of all the encompassed polynucleotides encoding variants of the polypeptide of SEQ ID NO:12 that retain the desired activity. Applicant has not described the properties or characteristics of variants, or polypeptide that share the retied percent identity to the protein of SEQ ID NO:12, that are required for the functional integrity of the protein. Furthermore, while recombinant techniques are available, it is not routine in the art to screen large numbers of polypeptides that might potentially retain the desired activity, because the expectation of obtaining similar activity is unpredictable. Thus one of skill in the art would require additional guidance, such as information as to what structural features would result in variants of the protein of SEQ ID NO:12, or nucleic acid encoding said variants which retain the desired activity. Thus, to practice the invention commensurate with the scope of the claims would result in undue experimentation.

Regarding claims 39-40, the instant specification only demonstrates that the polynucleotide of SEQ ID NO:11 encodes the polypeptide of the SEQ ID NO:12, which binds to GLP-2 ligand, therefore, the specification enables using a cell expressing said nucleic acid to identify ligands for the GLP-2 receptor of SEQ ID NO:12. However, the full scope of claims 39-40 is not enabled. Due to the large quantity of experimentation necessary to generate the infinite number of variants recited in the claims and possibly screen same for activity, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to same, the complex nature of the invention, the state of

the prior art which establishes the unpredictability of the effects of mutation on structure and function, and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Therefore, the instant specification is only enabling for the polynucleotide of SEQ ID NO:11, encoding the polypeptide of SEQ ID NO:12, a host cell that has been genetically engineered to incorporate and express said polynucleotide, and a method of identifying ligands for GLP-2 by using said cell.

4b. Claims 20, 27-32, 39-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Claim 20 encompasses nucleic acids which encode variants or mammalian homologs of the polypeptide of SEQ ID NO:12. Claims 27 and 41-43 encompass an isolated polynucleotide encoding a polypeptide having at least 95% to the polypeptide of SEQ ID NO:12, and claims 41-43 are drawn to a polynucleotide that is at least 80%, 90% or 95% to the polynuceltide of SEQ ID NO:11, which encodes a GLP-2 receptor that binds to GLP-2.. Claims 28-31 encompass an isolated polynucleotide which hybridizes under un-specified conditions to the nucleic acid of SEQ I NO:11. Claims 39-40 encompass method of identifying ligand for GLP-2 receptor, by using a cell expressing un-specified GLP-2 receptor. The claims do not require that the

polynucleotide or encoded polypeptide possess any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of polynucleotides that is defined only by sequence identity.

To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polynucleotides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the

method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481 at 1483. In Fiddes, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated polynucleotides of SEQ ID NO:11) encoding the polypeptide of SEQ ID NO:12, but not the full breadth of the claims meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections Under § 112, second paragraph:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 20-35, 37-38 and 41-43 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5a. Claim 20 recites in line 8, "...at least one amino acid substitution...", which renders the claim indefinite because there is no upper limit of how many amino acids to

substitute. The metes and bounds of the claim can not be ascertained. Appropriate correction is required.

5b. Claims 25-26 recite "... a polynucleotide which encodes for the human GLP-2 receptor and said polynucleotide encodes for the amino acid sequence of amino acids 1-553 of SEQ ID NO:12", it is unclear whether the claims is referring to one polynucleotide which encodes to human GLP-2 receptor and one that encodes the amino acid sequence of amino acids 1-553 of SEQ ID NO:12. The way the claims are drafted it appears that the human GLP-2 receptor and the amino acid sequence of amino acids 1-553 of SEQ ID NO:12 are two different molecules. Appropriate correction is required.

5c. Claims 28-31 are indefinite in the recitation of "hybridizes under conditions of high stringency ", however, there is no definition of which hybridization conditions are considered "high stringency" in the specification. The specification states that "stringency conditions are desirably enhanced to identify homologs having 90% or 95% identity", (top of page 7). Reciting the specific hybridization conditions, which Applicant considers to be "high stringency", that are supported by the specification in the claim would obviate this rejection.

Claims 20-24, 32-35, 37-38, 41-43 are rejected under 35 U.S.C. § 112, second paragraph so far as they depend on claim 20 for the limitations set forth directly above.

Conclusion:

7. No claim is allowed.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M. Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Fozia Hamud
Patent Examiner
Art Unit 1647
17 August 2006

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